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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,632	11/09/2005	Yves Rayssiguier	1487-27	4695

23117 7590 11/30/2007
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EXAMINER	
CRANE, LAWRENCE E	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
11/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,632	RAYSSIGUIER ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 14, 2007 (amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/14/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims **1-10** have been cancelled, no claims have been amended, the Abstract has been amended, and new claims **11-26** have been added as per the amendment filed September 14, 2007. One additional or supplemental Information Disclosure Statement (1 IDS) filed September 14, 2007 has been received with the single cited reference and made of record.

Claims **11-26** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **11-26** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the noted claims the terms "prevention," "anti-radical effect," and "anti-ageing" imply an effect or effects not adequately demonstrated by the written description of the instant disclosure. Therefore, applicant is respectfully requested to delete the noted terms or to substitute therefore by amendment terminology that is adequately supported by the written description.

Applicant's arguments filed September 14, 2007 have been fully considered but they are not persuasive.

Applicant's submission of a replacement claim set is noted. However, the term "prevention" in claim **11** implies a testing standard of the type applied to vaccines, a standard not met by any part of the instant disclosure. In addition the terms "anti-radical effect" and "anti-ageing" found in claims **22 and 23** are also representative of a theory that is little more than an unsubstantiated hypothesis based on a correlation. Neither instant applicant nor any presently cited prior art reference has provided anything more than correlation. And also neither the instant disclosure nor any prior art reference includes a disclosure or disclosures that convincingly proves the cause and effect on the aging process or its alleged cause and effect relationship with free radicals implied by the presence of the noted terms. This

conclusion appears to be shared by the authors of the reference **Sohal et al.** (supplied by application with the instant response) at page 584, column 1. Therefore the above rejection has been found to remain valid.

Claims **11** is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **11** at line 3, the term "prebiotics" renders the claim incompletely defined because the remainder of the claim fails to provide any definition of what particular substances are implied as active ingredients by this generic term.

Applicant's arguments with respect to claims **1-10** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendment.

Claims **22 and 23** are rejected under 35 U.S.C. §112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claims **22 and 23** are improperly dependent because the terms "anti-radical effect" and "anti-aging effect" refer to effects alleged to be inherent consequences of the claimed method and therefore said claims fail to further limit the subject matter of the claim from which they depend. Examiner respectfully suggests cancellation or other appropriate action.

Applicant's arguments with respect to claims **1-10** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendment.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **11-26** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Van Loo et al.** (PTO-892 ref. **U**) in view of **Beers et al.** (PTO-892 ref. **X**, excerpt from The Merck Manual).

The instant claims are directed to mixtures of fructose and fructooligosaccharides (FOS) in a food composition wherein the proportions of these two components can vary widely, and the administration of said compositions to treat "oxidative stress," aka over consumption of fructose and/or other quickly metabolizable monosaccharides wherein the overconsumption is alleged by the claims to be associated with ageing as a consequence of an increase in free-radical generation in vivo as a consequence of monosaccharide overconsumption.

Van Loo et al. discloses at page 535, column 1 that inulin and fructooligosaccharides (FOS) are not adsorbed from the mammalian intestine and therefore their only food value is a consequence of the heat generated by their subsequent partial consumption by intestinal flora in the latter portion of the small intestine. **Van Loo et al.** also discloses at Tables 1, 6, 9 and 10 numerous different food compositions containing mixtures of varying proportions of fructose and FOS, and also teaches at page 540, column 1 (paragraph beginning with "Literature Data"), that the relative proportions of fructose and FOS can be adjusted by heating (roasting). At pages 536-546 this reference lists a variety of food stuffs wherein FOS is a naturally occurring component part. At page 550, column 1, second full paragraph, this reference also discloses that the average U.S. human consumptions of fructose and FOS intake are 7 grams/day and 7-20 grams/day, respectively.

Van Loo et al. does not expressly disclose the precisely limiting proportions of fructose and FOS to be present in a food composition or disclose that consumption of greater proportions of FOS relative to fructose has health benefits associated with a reduction of "oxidative stress," aka over production of free radicals or other consequences of the over consumption of monosaccharides including fructose.

Beers et al. discloses at pages 58-62 that obesity is a major cause of health problems and at page 61 (Prognosis and Treatment) counsels the necessity of reducing caloric intake as an essential part of effectively treating this problem. This reference does not mention the details of food compositions, but does mention limitation of caloric intake as a measure used by weight management programs to reduce weight over time.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to reduce the ill-effects of the over consumption of readily adsorbed monosaccharides (overweight, high blood sugar, high blood lipid levels, high blood pressure, atherosclerosis, etc.) by the reduction of the proportion of these substances in food compositions, including by adoption of food compositions of the kinds disclosed in **Van Loo et al.** wherein inulin and associated fructooligosaccharide mixtures (FOS) are present along with monosaccharides including fructose in both naturally occurring and processed food compositions. The introduction of mechanistic explanations wherein terms like "oxidative stress" are presented does not change the well established fact that over consumption of food compositions causes health problems, and that reduction of this consumption, including reduction of the consumption of monosaccharides like fructose, is one step the ordinary practitioner can take to avoid one or more of the negative medical consequences listed above. The **Beers et al.** reference confirms this view.

Therefore, the instant claimed fructose plus fructooligosaccharide (FOS) food compositions and the effect of the administration of these compositions as part of a calorie restricted diet, wherein the total quantity of monosaccharides consumed by the host being treated for "oxidative stress" (aka over consumption of monosaccharides) is reduced, would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

Applicant's arguments filed September 14, 2007 have been fully considered but they are not persuasive.

Applicant has argued in what appears to be a circular or a conclusory manner that the new claim set is not obvious in view of the previously cited prior art. However, the instant disclosure fails to provide any non-prospective guidance permitting one of ordinary skill to determine what proportions of what are all known in the art substances must be, or should be, incorporated into the claimed compositions to achieve the results claimed by the method claims. Therefore, the selection of proportions of the ingredients listed in the instant claims remains open to all who would explore this area and are not effectively limited by a showing in the instant disclosure that applicant has actually reduced to practice the claimed method by defining any set or any sets of active ingredient proportions that has been shown by appropriate

test data to have the claimed medicinal effect. Therefore, the above rejection is deemed to continue to apply to the new claim set.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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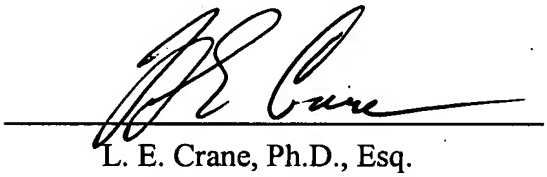
11/27/2007



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